

## REMARKS

This communication is submitted in response to the Office Action dated April 26, 2006.

Claims 1-28 are pending in the subject patent application and have not been amended. Claims 29-46 which were withdrawn from consideration by the Examiner as being directed to a non-elected invention have been canceled herewith.

The specification has been amended to modify the title to conform with the subject matter of the claims remaining in the application. The specification has been further amended to delete reference to objects of the invention, since the claimed invention is not limited and should not be construed to be limited to only those objects originally enumerated in the specification.

Reconsideration of the subject application is respectfully requested in view of the foregoing amendments and the following remarks.

The rejection of claims 1-28 as being unpatentable over Drongelen is respectfully traversed for the following reasons.

Independent claim 1 recites "a stimulator powered by said power source to deliver a complete cycle of biphasic electrical stimulation for application to anatomical tissue, said stimulator delivering said complete cycle of biphasic electrical stimulation as a first group of a selected number of positive or negative pulses automatically followed by a second group of a selected number of pulses of reverse polarity to said pulses of said first group." In support of the rejection of claim 1, the Examiner asserts that the system of Drongelen is inherently capable of delivering biphasic electrical stimulation since it is "well known that conventional electrical stimulators are capable of biphasic

electrical stimulation by cathodal stimulation and anodal stimulation". The Examiner's assertion is considered to be without merit. In the system of Drongelen, the stimulation provided by stimulator 50 is controlled by the monitoring system 30, and there are absolutely no teachings or suggestions whatsoever by Drongelen that the monitoring system 30 has the capability of controlling the stimulator 50 to deliver biphasic electrical stimulation. Indeed, Drongelen discloses that the polarity of audio stimulation can be controlled by the monitoring system 30 (column 16, lines 58-59, "duration, polarity, transducer, and decibels, for each of left and right auditory stimulators") but does not mention this among the various parameters that can be controlled by the monitoring system for electrical stimulation (column 16, lines 56-58, "duration, type, maximum intensity, intensity, stimulus site, mode, train rate, etc., for electrical stimulators"). The fact that Drongelen specifically omitted polarity or phase as one of the parameters that could be controlled by the monitoring system for electrical stimulation, yet specifically mention the same parameter as being controllable by the monitoring system for audio stimulation demonstrates that Drongelen in fact did not consider the monitoring system 30 as having the capability attributed to it by the Examiner. Furthermore, the Examiner's self-proclaimed conclusionary statement regarding the capability of conventional electrical stimulators to deliver biphasic electrical stimulation does not provide the objective factual basis needed to support an obviousness rejection. Even assuming the existence of conventional electrical stimulators capable of biphasic electrical stimulation, it cannot properly be inferred that the system of Drongelen necessarily and inherently possesses this capability in the absence of any teachings or suggestions in Drongelen to support the inference. In relying on inherency, the

Examiner must provide a basis in fact and/or technical reasoning to support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the prior art. Ex parte Levy, 17 USPQ 2d 1461 (Bd. Pat. Appls. and Int. 1990). The Examiner has not fulfilled the latter requirement and, on the contrary, has tainted the factual determination of inherency with impermissible conjecture.

The Examiner acknowledges in the Office Action that Drongelen does not disclose stimulators have the feature of delivering a complete cycle of biphasic electrical stimulation as a first group of a selected number of positive or negative pulses automatically followed by a second group of a selected number of pulses of reverse polarity to the pulses of the first group, and maintains it would have been a simple matter of “well-known electromechanical configuration” to incorporate this feature in the system of Drongelen. Again, the Examiner has failed to proffer any factual or evidentiary support for the “well-known electromechanical configuration” by which the system of Drongelen could be configured to deliver a complete cycle of biphasic electrical stimulation as a first group of a selected number of positive or negative pulses automatically followed by a second group of a selected number of pulses of reverse polarity to the pulses of the first group. The only support provided by the Examiner regarding the teachings of the prior art is the Examiner’s own broad conclusionary statement which fails to provide the factual basis needed to support an obviousness rejection. The Examiner’s assertion that it would have been obvious to reconfigure the system of Drongelen to include the indeterminable “well-known electromechanical configuration” is also unfounded because no motivation is provided in the prior art to support the reconfiguration of Drongelen proposed by the Examiner. The motivation

given by the Examiner in support of reconfiguring the system of Drongelen in fact comes from applicants' disclosure and not from the teachings of the prior art. Whereas applicants recognized a number of problems to be solved by the claimed invention, among them the problem relied on by the Examiner as providing motivation for reconfiguring the system of Drongelen, neither Drongelen nor the indeterminable "well-known electromechanical configuration" recognize any such problems and do not provide any motivation or support for modifying Drongelen in the manner proposed by the Examiner.

It is fundamental that rejection under 35 USC §103 must be based on evidence. In re Grasselli, 713 F. 2d 731, 218 USPQ 769 (Fed. Cir. 1983), and the Examiner has the burden under Section 103 of providing the evidence necessary to establish a prima facie case of obviousness. In re Piasecki, 745 F. 2d 1468, 223 USPQ 785 (Fed. Cir. 1984). Allegations of obviousness without supporting evidence are improper in a rejection. In re Spoormann and Heinke, 150 USPQ 449 (CCPA 1966). The Examiner's reliance on "conventional electrical stimulators" and "well-known electromechanical configuration" does not satisfy the evidentiary requirement needed to establish a prima facie case of obviousness. The "conventional electrical stimulators" and "well-known electromechanical configuration" referred to by the Examiner are merely unfounded assumptions that make it impossible to determine the scope and content of the prior art and the differences between the prior art devices and the claimed invention, all of which are relevant facts in the determination of obviousness. Graham v. John Deere Co., 383 US 1, 148 USPQ 459 (1966). The Examiner has clearly resorted to speculation, unfounded assumption and hindsight reconstruction to supply deficiencies in the factual

basis, and it is improper to taint the factual determination of obviousness in this manner. In re Warner, 154 USPQ 173 (CCPA 1967), cert. denied, 389 US 1057 (1968).

In addition to the foregoing improprieties, the Examiner has improperly used applicants' invention as an instruction manual or template to render the claimed invention obvious. Ex parte Haymond, 41 USPQ 2d 1217 (Bd. of Pat. Appls. and Int. 1996). It is well established that the motivation to combine references cannot come from the invention itself. In re Oetiker, 24 USPQ 2d 1443 (Fed. Cir. 1992). Yet, in the present case, the motivation set forth by the Examiner in support of modifying Drongelen in accordance with unsubstantiated teachings of the prior art comes only from applicants' disclosure.

In light of the foregoing, the rejection of independent claim 1 as being unpatentable over Drongelen is considered to be improper. Independent claim 1 is thusly submitted to be clearly patentable over Drongelen and should be allowed along with its dependent claims 2-11.

The Examiner disposes of claims 2, 3, 5, 7 and 9 as claiming "intended uses" that are capable of being performed by the system of Drongelen. On the contrary, the limitations recited in claims 2, 3, 5, 7 and 9 impart structural limitations to the claimed stimulator that are not disclosed or suggested by Drongelen. Drongelen does not explicitly or inherently disclose the stimulator 50 to deliver a complete cycle of biphasic electrical stimulation and alternatively a complete cycle of monophasic electrical stimulation as recited in claim 2. As pointed out above, Drongelen fails to disclose any capability for the monitoring system 30 to control the stimulator 50 to deliver a complete

cycle of biphasic electrical stimulation, much less for the same stimulator to alternatively deliver a complete cycle of monophasic electrical stimulation. The additional limitations recited in claims 3, 5, 7 and 9 pertaining to specific features of the biphasic and monophasic electrical stimulation are not disclosed or suggested by Drongelen. Accordingly, dependent claims 2, 3, 5, 7 and 9 are submitted to be clearly patentable over Drongelen for the additional limitations recited therein as well as being patentable with independent claim 1.

Dependent claims 4, 6, 8 and 10 recite specific limitations pertaining to the current amplitude, number of pulses, duration, and delay between pulses for the biphasic and monophasic electrical stimulation delivered by the claimed stimulator. None of the limitations recited in claims 4, 6, 8 and 10 are disclosed by Drongelen but are considered by the Examiner to be matters of obvious design. Applicants dispute the Examiner's contention that the recited features are matters of obvious design. The recited features can only be considered matters of obvious design by engaging in hindsight reconstruction made possible from the claimed invention itself. Accordingly, dependent claims 4, 6, 8 and 10 are submitted to be clearly patentable over Drongelen for the additional features recited therein as well as being allowable with independent claim 1.

Claim 11 recites "said power source comprises a power console electrically connectible to said stimulator". The Examiner maintains that, first of all, a power source is inherent to the system of Drongelen and, second of all, that the power source and a power console can be considered the same thing. While it is conceded that the monitoring system 30 of Drongelen would require a power source to operate, it does not

follow that the power source is a power console. The central component of Drongelen's monitoring system 30 is a conventional computer system, i.e. conventional personal computer 32, which conventionally would be powered from an electrical wall outlet bearing no correspondence to a power console. Having failed to disclose a power console, Drongelen cannot be disclosing a power console electrically connectible to the stimulator 50. Claim 11 is thusly submitted to be clearly patentable over Drongelen for the additional limitations recited therein as well as being allowable with independent claim 1.

Independent claim 12 recites "a stimulator ... to deliver a complete cycle of biphasic electrical stimulation ..., said stimulator delivering said complete cycle of biphasic stimulation as a first group of one or more positive or negative pulses followed by a second group of one or more pulses of opposite polarity to said pulses of said first group; and an activator actuatable by a user to complete an activation that starts delivery of said first group of pulses, said activation being effective to deliver said complete cycle of biphasic electrical stimulation." As pointed out above in connection with independent claim 1, Drongelen fails to teach or suggest the stimulator 50 delivering a complete cycle of biphasic electrical stimulation. Moreover, Drongelen fails to teach or suggest an activator actuatable by a user to complete an activation that starts delivery of a first group of one or more positive or negative pulses of biphasic electrical stimulation and is effective to deliver a complete cycle of biphasic electrical stimulation in which the first group of pulses is followed by a second group of one or more pulses of opposite polarity. The Examiner equates the keyboard 34 of the monitoring system 30 of Drongelen as corresponding to the recited activator. However,

Drongelen does not even disclose the keyboard as initiating delivery of electrical stimulation but only its use to establish stimulus settings. There are no teachings or suggestions whatsoever by Drongelen of the keyboard 34 being actuatable by a user to complete an activation that starts delivery of a first group of positive or negative one or more positive or negative pulses and is effective to deliver a complete cycle of biphasic electrical stimulation in which the first group of pulses is followed by a second group of pulses of opposite polarity to the pulses of the first group. On the contrary, the system of Drongelen requires that the active panel displayed on the computer monitor be changed to a different active panel each time the stimulus context, which establishes the characteristics of the stimulus, is to be changed. In the system of Drongelen, neither the keyboard 34 nor any other activator is actuatable by a user to complete an activation that starts delivery of a first group of positive or negative pulses and is effective to deliver a complete cycle of biphasic electrical stimulation. From a practical standpoint, changing the active panel to a different active panel each time the characteristics of the stimulus are to be changed has the same disadvantages as the system of Drongelen is the repetitive manual operation of a mechanical switch discussed in the subject application. The present invention, in contrast, allows a complete cycle of biphasic electrical stimulation delivered as a first group of positive or negative pulses followed by a second group of pulses of opposite polarity to be delivered by a stimulator in response to a single complete activation of an activator. Independent claim 12 is thusly submitted to be clearly patentable over Drongelen and should be allowed along with dependent claims 13-16.

With respect to dependent claim 13, the Examiner submits that the keyboard 34



of Drongelen is inherently actuatable to complete the activation in a two-step procedure such as pressing a button and releasing the button. Applicants disagree. As pointed out above in connection with independent claim 12, Drongelen requires that a different active panel, and its stimulus context, be selected for each difference or change in stimulation. Assuming each selection of an active panel requires pressing a button and releasing the button, delivering two different forms of stimulation in the system of Drongelen by selecting two different active panels would require at least a four-step procedure. It is thusly submitted that claim 13 is clearly patentable over Drongelen for the additional limitations recited therein as well as being allowable with independent claim 12.

With respect to claim 14, Drongelen fails to disclose an activator as claimed in claims 12 and 13, much less a “hand switch” as recited in claim 14. Accordingly, dependent claim 14 is submitted to be clearly patentable over Drongelen for the further limitation recited therein as well as being allowable with claim 12.

Dependent claim 15, which recites a power console as well as the activator comprising a control option on a touch screen of the power console, is submitted to be patentable over Drongelen for the reasons discussed above in connection with claims 11, 12 and 13.

Dependent claim 16 recites “said stimulator is powered by said power source to alternatively deliver a complete cycle of monophasic electrical stimulation ..., said stimulator delivering said complete cycle of monophasic electrical stimulation as one or more positive or negative pulses, and said activation is effective to deliver said complete cycle of monophasic electrical stimulation.” As noted above in connection

with dependent claim 2, there are no teachings or suggestions whatsoever by Drongelen of the monitoring system 30 having the capability of controlling the stimulator 50 to deliver a complete cycle of biphasic electrical stimulation and to alternatively deliver a complete cycle of monophasic electrical stimulation. It follows that Drongelen does not and cannot disclose or suggest an activator effective to deliver a complete cycle of biphasic electrical stimulation and alternatively a complete cycle of monophasic electrical stimulation. Accordingly, claim 16 is submitted to be clearly patentable over Drongelen for the additional limitations recited therein as well as being allowable with independent claim 12.

Independent claim 17 calls for “a power console providing a power source and a display screen; a patient interface unit electrically connectable to said power console, said patient interface unit being connectible to monitoring electrodes ... to detect responses to a first form of electrical stimulation and a second form of electrical stimulation ..., said patient interface unit being connectible to monopolar and bipolar stimulating probes for applying said first form of electrical stimulation ..., said patient interface unit delivering said first form of electrical stimulation up to a current amplitude of about 30 mA; and a stimulator electrically connectible to said power console, said stimulator being connectible to a pair of stimulating electrodes ... for applying said second form of electrical stimulation to ... the patient, said stimulator delivering said second form of electrical stimulation to a first one of the stimulating electrodes for return via a second one of the stimulating electrodes in a positive phase ... and delivering said second form of electrical stimulation to the second one of the stimulating electrodes for return via the first one of the stimulating electrodes in a negative phase ..., said

stimulator delivering said second form of electrical stimulation up to a current amplitude of about 200 mA." Drongelen does not disclose or suggest a power console providing a power source and a display screen, as well as a patient interface unit connectible to the power console. In the monitoring system 30 of Drongelen, the computer provides a display screen and the various user interfaces disclosed by Drongelen are themselves display windows that appear on the display screen of the computer. Drongelen does not disclose or suggest a separate patient interface unit that is an actual hardware component connectible to a power console and also connectible to monitoring electrodes and to monopolar and bipolar stimulating probes for applying a first form of electrical stimulation. Drongelen fails to demonstrate any contemplation whatsoever for the monitoring system 30 to be connectible to monopolar and bipolar stimulating probes, which is distinctly different from the stimulator 50 disclosed by Drongelen as being connected to the patient via electrodes attached to the patient. Rather, monopolar and bipolar stimulating probes are recognized in the medical field as being hand-held instruments having tips that are briefly held in contact with anatomical tissue to be stimulated. It cannot be considered obvious to modify the system of Drongelen for connection to monopolar and bipolar stimulating probes in the absence of any teachings or suggestions whatsoever as to how such a modification would be technically implemented. Since the user interfaces disclosed by Drongelen are windows that appear on the display screen of the computer, it cannot be considered obvious from Drongelen's use interfaces to provide a separate patient interface unit connectible to monopolar and bipolar stimulating probes. Furthermore, the patient interface unit as recited in independent claim 17 is required to deliver the first form of

electrical stimulation, and in the system of Drongelen the computer that implements the user interface display screens does not itself deliver electrical stimulation, much less electrical stimulation up to the current amplitude recited for the patient interface unit in claim 17. The features recited in claim 17 pertaining to the stimulator delivering the second form of electrical stimulation are not disclosed or suggested by Drongelen for the reasons discussed above in connection with independent claim 1. The total combination of features recited in independent claim 17 are not disclosed or suggested by Drongelen and can only be considered obvious over Drongelen using the invention itself as an instruction manual or template to piece together isolated teachings of the prior art. This type of hindsight, piecemeal reconstruction is impermissible. Ex parte Haymond, 41 USPQ 2d 1217 (Bd. of Pat. Appls. and Int. 1996); In re Warner, 154 USPQ 173 (CCPA 1967), cert. denied, 389 US 1057 (1968). The prior art relied on by the Examiner not only fails to provide the teachings needed in order to reconstruct Drongelen to arrive at the claimed invention but also fails to provide any motivation to support reconstructing Drongelen in the manner proposed by the Examiner. Independent claim 17 is thusly submitted to be clearly patentable over Drongelen and should be allowed along with its dependent claims 18-28.

Dependent claims 18-20 recite additional limitations pertaining to the first and second forms of electrical stimulation, none of which are taught or suggested by Drongelen within the reasonable metes and bounds of its disclosure. Accordingly, claims 18-20 are submitted to be clearly patentable over Drongelen for the limitations recited therein as well as being allowable with independent claim 17.

With respect to dependent claim 22, it is noted that the Examiner equates the

keyboard of Drongelen to the claimed activator but, for the reasons discussed above in connection with claims 12-16, Drongelen fails to disclose the keyboard as having the features of the claimed activator. Accordingly, dependent claim 22 is submitted to be clearly patentable over Drongelen for the additional features recited therein as well as being allowable with independent claim 17.

Claim 23 recites additional limitations pertaining to the patient interface unit and, as pointed out above, Drongelen fails to disclose a patient interface unit much less one having a plurality of monitoring channels each connectible to a pair of monitoring electrodes as recited in claim 23. Claim 23 is thusly submitted to be clearly patentable over Drongelen for the additional limitations recited therein as well as being allowable with claim 17.

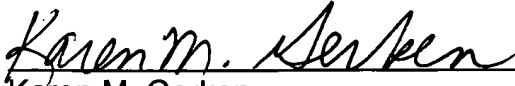
Various limitations relating to the display of waveforms representing responses detected by the monitoring electrodes for the first and second forms of electrical stimulation are recited in claims 24-27 and are not disclosed or suggested by Drongelen given that Drongelen fails to contemplate both forms of electrical stimulation. It is submitted, therefore, that dependent claims 24-27 are clearly patentable over Drongelen for the additional limitations recited therein as well as being allowable with independent claim 17.

Claim 28 is submitted to be patentable over Drongelen for the further limitations recited therein, as well as being allowable with claim 17, for the reasons discussed above in connection with claim 15.

In light of the foregoing, all the claims in the subject patent application are submitted to be in condition for allowance. Action in conformance therewith is

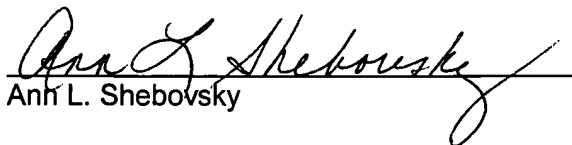
courteously solicited. Should any issues in the subject application remain unresolved, the Examiner is encouraged to contact the undersigned attorney.

Respectfully submitted,

  
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I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop: Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on July 26, 2006.

  
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